IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

ENDO PHARMACEUTICALS INC., Plaintiffs, v. ROXANE LABORATORIES, INC., Defendants.	C.A. No. 13-cv-3288-TPG
ENDO PHARMACEUTICALS INC. and GRÜNENTHAL GMBH, Plaintiffs, v. AMNEAL PHARMACEUTICALS, LLC and AMNEAL PHARMACEUTICALS OF NEW YORK, LLC, Defendants.	C.A. No. 12-cv-8115-TPG
ENDO PHARMACEUTICALS INC. Plaintiffs, v. RANBAXY LABORATORIES LTD., RANBAXY INC. and RANBAXY PHARMACEUTICALS INC., Defendants.	C.A. No. 13-cv-8597-TPG

ENDO PHARMACEUTICALS INC. Plaintiffs, v. RANBAXY LABORATORIES LTD., RANBAXY INC. and RANBAXY PHARMACEUTICALS INC., Defendants.	C.A. No. 13-cv-4343-TPG

REPLY BRIEF IN SUPPORT OF DEFENDANTS' MOTION FOR REDUCTION IN THE NUMBER OF ASSERTED CLAIMS

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I. INTRODUCTION

Endo's opposition brief repeatedly represents that Endo has reduced the number of claims in this case. (*See, e.g.*,D.I. 89 at 4.) It has not: Endo has said that it would reduce the number of claims it is asserting only if Defendants accept the draconian and one-sided terms of a case management order that Endo proposed that would limit Defendants to asserting almost no prior art in their invalidity case. Failing that capitulation, Endo is still asserting the same 72 largely duplicative patent claims addressed in Defendants' Motion.

Endo has already identified at least 44 claims that it could eliminate without materially affecting its case. (*See e.g.* Ex[1].T, Sept. 3, 2014 Loeb ltr. to Goodin; Ex. U, Sept. 3, 2014 ltr. to Cruz.) Further, Endo openly admits that Defendants have identified redundancies in the claims. (D.I. 89 at 4.) Moreover, Endo does not even try to argue that any of its asserted claims provide separate and unique issues of noninfringement or invalidity. (D.I. 89.)

Defendants have demonstrated that the claims asserted are unnecessarily duplicative and burdensome—Defendants should not have to waste the time and money of having their experts address claims that will never be asserted. Moreover, Defendants have shown that Endo's proposed case management order proposing to limit Defendants' assertion of prior art to those few exemplary references discussed at the February 20, 2014 and April 2, 2014 conferences is unfair and unreasonable. Because it is necessary to reduce the case to a manageable number of claims before the parties serve their opening expert reports, the Court should grant Defendants' Motion and direct Endo to reduce its number of asserted claims to no more than five per patent.

[1] "Ex.__" refers to the Exhibits to the Declaration of Paul Sudentas in Support of the Reply Brief in Support of Defendants' Motion for Reduction in the Number of Asserted Claims.

II. ARGUMENT

A. Endo Has Not Reduced the Number of Asserted Claims

Endo is still asserting all 72 claims addressed in Defendants' Motion, despite its representation to the Court that "***Endo is not currently asserting any of the allegedly redundant claims.***" (D.I. 89 at 4.) On September 3, 2014, just a week before filing its Opposition, Endo sent Defendants letters proposing to limit the 72 asserted claims from the '122, '216 and '482 patents to 28:

'122 patent claims: 2, 3, 18, 19, 20;
'216 patent claims: 1, 22, 38, 40, 42, 44, 47, 50, 54, 57, 59, 62, 64, 71, 72, 73, 74, 77, 78, 79, 80, 82;
'482 patent claim: 4

(*See e.g.* Ex.T, Sept. 3, 2014 Loeb ltr. to Goodin; Ex. U, Sept. 3, 2014 ltr. to Cruz.) Endo's September 3 proposal, however, also stated that the narrowed list of claims was conditioned on Defendants accepting the proposed case management order that Endo submitted on August 14, 2014. (*Id.*)

Defendants oppose the conditions of Endo's August 14 proposed case management order (D.I. 77) for the reasons provided in Defendants' August 28 letter to the Court (D.I. 78.). Endo's case management order attempts to limit Defendants' arguments, prior art, and expert testimony to only the issues discussed at the conference, which were made before Endo made any attempt to reduce the claims in the case. Endo's arguments put the cart before the horse. Common sense dictates that reduction in prior art comes after reductions in the number of claims.[2] Additionally,

[2] Once Endo properly reduces the number of asserted claims, Defendants can then reduce their prior art references accordingly. *See, e.g., Masimo Corp. v. Philips Electronics N. Am. Corp.*, 918 F. Supp. 2d 277, 284-286 (D. Del. 2013) (holding that common sense requires plaintiff first to limit the number of claims and claim terms it is asserting before the defendant must limit the number of prior art references).

did not have sufficient time at the conference to address the more than 130 claims asserted and clearly represented to Endo and to the Court that the arguments made were intended as *examples*. (*Id*. at 2.)

Endo's opposition portrays it as willing party who is negotiating in good faith to limit the issues for trial, but that is not the case. Endo's September 3 proposal demonstrates that, while Endo *can* limit its claims at this point in the litigation, it is unwilling to do so without first trying to leverage the reduction in claims to impose draconian and prejudicial limits on Defendants.

B. Endo Has Not Identified Any Unique and Separate Issues of Validity or Infringement for its 72 Asserted Claims or its 28 Proposed Claims

Endo admits that Defendants' Motion correctly identifies redundancies in the claims asserted, declaring "Endo has already limited its claims to eliminate the redundancies that Moving Defendants identify in their motion" and listing claims as 13, 21, 23, 24-30, 36, 41, 49 and 66 as the eliminated claims. (D.I. 89 at 4.) Endo further confirms that its asserted claims are redundant, by stating that it would not proceed with claims 31, 35 and 37 because these claims are redundant with claims 38, 40 and 42. (*Id.*) Defendants have provided many examples of duplicative claims in the asserted patents. Under *Katz*, Endo is now required to show that the asserted claims raised unique questions of validity and/or infringement. *In re Katz Interactive Call Processing Patent Litig.*, 639 F.3d 1303, 1312-13 (Fed. Cir. 2011). "While different claims are presumed to be of different scope, that does not mean that they necessarily present different questions of validity or infringement." *Id.* at 1313. Endo has failed to do so.

Endo does not argue—because it *cannot*—that each of the 72 claims still asserted present unique and separate issues of validity and/or infringement. With respect to infringement, Endo makes a passing reference to Defendants' formulations having different "recipes," claiming that it has "tailored" its asserted claims to each specific product, but then revealingly admits that it

intends to assert the same 26 claims against all eight defendants in this case. (D.I. 89 at 2.)

In fact, all three Defendants joining this motion received proposals from Endo with identical claims Endo proposed to be asserted against them. (*See e.g.* Ex.T, Sept. 3, 2014 Loeb ltr. to Goodin; Ex. U, Sept. 3, 2014 ltr. to Cruz.) Further, Endo cannot argue that all 72 claims asserted provide unique issues of invalidity. As Endo has already conceded, it could reduce the currently asserted claims by at least 44 claims without materially affecting its case. (*See e.g.* Ex.T, Sept. 3, 2014 Loeb ltr. to Goodin; Ex. U, Sept. 3, 2014 ltr. to Cruz.) Moreover, Endo has not identified any issues for expert discovery or claim construction that once decided would create separate and unique issues of noninfringement or invalidity for each of the asserted claims.

C. Endo Should Reduce the Number of Claims to No More Than Five Per Patent

Even if Endo does reduce the 72 claims currently asserted to the 28 identified in its September 3 proposal, many of the redundancies identified by Defendants' Motion will still exist as set forth in the examples below:

The '122 patent:

Although Endo proposes eliminating independent claim 1 in its September 3 proposal, it still intends to assert claims 2 and 3, which incorporate the limitations of claim 1. Therefore, the redundancies that exist between claims 1-3 and claim 19 will still exist under Endo's proposal.

Claims 1-4	**Claim 19**
[1. An analgesically effective controlled release pharmaceutical composition with a twelve hour dosing interval in the form of a tablet,	19. An analgesically effective controlled release pharmaceutical composition with a twelve hour dosing interval in the form of a tablet,
comprising oxymorphone or a pharmaceutically acceptable salt thereof as the sole active ingredient in the tablet,	comprising oxymorphone or pharmaceutically acceptable salt thereof as the sole active ingredient in the tablet

and a controlled release delivery system comprising at least one pharmaceutical excipient,	and a controlled release delivery system comprising a hydrophilic material that forms a gel upon exposure to gastrointestinal fluid,
wherein upon placement of the composition in an in vitro dissolution test comprising USP Paddle Method at 50 rpm in 500 ml media having a pH of 1.2 to 6.8 at 37° C., about 15% to about 50%, by weight, of the oxymorphone or salt thereof is released from the tablet at about 1 hour in the test.]	wherein upon placement of the composition in an in vitro dissolution test comprising USP Paddle Method at 50 rpm in 500 ml media having a pH of 1.2 to 6.8 at 37° C., about 15% to about 50%, by weight, of the oxymorphone or salt thereof is released from the composition at about 1 hour in the test,
2. The pharmaceutical composition of claim 1 wherein about 45% to about 80%, by weight, of the oxymorphone or salt thereof is released from the tablet at about 4 hours in the test.	about 45% to about 80%, by weight, of the oxymorphone or salt thereof is released from the composition at about 4 hours in the test,
3. The pharmaceutical composition of claim 1 wherein at least about 80%, by weight, of the oxymorphone or salt thereof is released from the tablet at about 10 hours in the test.	and at least about 80%, by weight, of the oxymorphone or salt thereof is released from the composition at about 10 hours in the test.

The ‘216 patent:

Although Endo’s September 3 proposal proposes to eliminate independent claims 49 and 66, it still includes claims 54 and 71, which are nearly identical claims depending from claims 49 and 66, respectively. Endo’s September 3 proposal therefore, does not limit the claims sufficiently to address the redundancies identified in Defendants’ Motion:

Claim 54	**Claim 71**
[49. An analgesically effective controlled release pharmaceutical composition for oral delivery, comprising:	[66.An analgesically effective controlled release pharmaceutical composition for oral delivery, comprising:
a. a controlled release delivery system with a release rate profile designed to provide adequate blood plasma levels over at least 12 hours to provide sustained pain relief over this same period; and	a. a controlled release delivery system with a release rate profile designed to provide adequate blood plasma levels over at least 12 hours to provide sustained pain relief over this same period; and
b. about 5 mg to about 80 mg of oxymorphone or a pharmaceutically acceptable salt of oxymorphone, wherein oxymorphone is the sole active	b. about 5 mg to about 80 mg of oxymorphone or a pharmaceutically acceptable salt of oxymorphone, wherein oxymorphone is the sole active

ingredient,	ingredient,
wherein upon oral administration of a single dose of the composition to a human subject, the oxymorphone C_{max} is at least 50% higher when the dose is administered to the subject under fed as compared to fasted conditions, and wherein upon placement of the composition in an in vitro dissolution test comprising USP Paddle Method at 50 rpm in 500 ml media having a pH of 1.2 to 6.8 at 37° C., about 15% to about 50%, by weight, of the oxymorphone or salt thereof is released from the tablet at about 1 hour in the test.]	wherein upon placement of the composition in an in vitro dissolution test comprising USP Paddle Method at 50 rpm in 500 ml media having a pH of 1.2 to 6.8 at 37° C., about 15% to about 50%, by weight, of the oxymorphone or salt thereof is released from the tablet at about 1 hour in the test, and wherein upon oral administration of the composition to a human subject, the blood plasma levels of oxymorphone comprise one or more peaks.]
54. The composition of claim 49 wherein about 45% to about 80%, by weight, of the oxymorphone or salt thereof is released from the tablet at about 4 hours in the test, and at least about 80%, by weight, of the oxymorphone or salt thereof is released from the tablet at about 10 hours in the test.	71. The composition of claim 66 wherein the composition is in the form of a tablet and about 45% to about 80%, by weight, of the oxymorphone or salt thereof is released from the tablet at about 4 hours in the test, and at least about 80%, by weight, of the oxymorphone or salt thereof is released from the tablet at about 10 hours in the test.

Because Endo's September 3 proposal still includes many duplicative and redundant claims and claim limitations, Endo should further reduce its claims to no more than five claims per patent to avoid the unnecessary and time consuming task of addressing each of these claims.

Endo is also incorrect to state that addressing excessive duplicative claims is not a burden to Defendants. Endo argues that *In re Brimonidine* is not relevant to the current dispute because it relates only to whether Defendants had presented invalidity arguments on a claim-by-claim basis "***at trial***." (D.I. 89 at 5 (emphasis in original).) Endo fails to appreciate that *In re Brimonidine* also addresses a District Court's ability to require expert testimony to support any argument made in support of invalidity. *In re Brimonidine Patent Litig.*, 643 F.3d 1366, 1376 (Fed. Cir. 2011). The Federal Circuit held that it is well within a trial judge's discretion to require expert testimony supporting technical references that are relied on to establish obviousness and held that the district court did not abuse its discretion in refusing to consider

obviousness arguments in light of the absence of testimony. (*Id.*) Moreover, the entire point of reducing claims is to reduce the burden "***at trial***." That starts with the expert reports, and is precisely what the instant motion is aimed to achieve – reducing the number of claims at trial so a claim-by-claim invalidity argument does not need to be made on an inordinate number of patent claims that are highly duplicative, wasting both the parties' and the Court's time.

D. Now is the Right Time to Limit the Number of Claims

Both parties have submitted proposed schedules that call for opening expert reports to be submitted no later than October 2014. Given these upcoming deadlines, it is appropriate for the parties to limit the issues for trial now to reduce the burden on the Court going forward.

Endo suggests that there is case law that supports waiting until after claim construction to reduce the number of asserted claims. (D.I. 89 at 6.) However, Endo's argument makes little sense given that claim construction in this case is set to take place at trial. Waiting until after claim construction in the present case would mean that Endo would not reduce the number of claims until several days after trial had commenced. The Court should not be required to waste its time and energy construing claims only to have Endo drop them after claim construction.

Case law overwhelmingly supports reducing the number of claims before a *Markman* hearing is perfectly appropriate to reduce claim construction issues. The Federal Circuit has upheld a district court's order to reduce the number of claims before a *Markman* hearing. *See Stamps.com Inc. v. Endicia Inc. et al.*, 437 Fed. Appx. 897, 900 (Fed. Cir. 2011). In addition, other district courts have ordered patentees to reduce their number of asserted claims before a *Markman* hearing. The *High Point Sarl* court held before claim construction that "the time for identifying critical issues and for narrowing the scope of the litigation, if not passed, is now" where plaintiff had not identified any claims that once construed would be outcome determinative. *High Point Sarl v. Sprint Nextel Corp.*, No. 09-2269-CM-DJW, 2010 U.S. Dist.

LEXIS 85497, *11-12 (D. Kan. Aug. 18, 2010) (reduction of 117 claims to 20). The court in *Masimo Corp. v. Philips Electronics N. Am. Corp*., 918 F. Supp. 2d 277 (D. Del. 2013) held that reducing the number of claims before claim construction "would reduce the overall complexity of the case because: 1) that reduction would likely reduce the number of claim disputes…" *Id.* at 279; n. 14; *see also Adobe Systems Inc. v. Wowza Media Systems, LLC*, No. 11-cv-02243, 2013 U.S. Dist. LEXIS 65049, at *3-4(N.D. Cal. May 6, 2013) ("the court sees little reason to construe terms and rule on summary judgment motions that relate to claims that Adobe will not be asserting at trial. The court therefore orders Adobe to limit its asserted claims in this action to twenty representative claims."); *Fenster Family Patent Holdings, Inc. v. Siemens Med. Solutions*, No. 04-0038-JJF, 2005 U.S. Dist. LEXIS 20788, at *5 (D. Del. Sep. 20, 2005).(ordering that plaintiffs the number of claims weeks in advance of a scheduled *Markman* hearing.)

The orders Endo cites denying motions for a reduction of claims do not apply here. Both orders deny the motion without prejudice and allow for the defendants to resubmit a motion to reduce claims after *Markman* but before the submission of opening expert reports. *See Thomas Swan & Co., Ltd., v. Finisar Corp.,* No. 13-cv-178 (E.D. Tex. Apr. 10, 2014) (D.I. 90 at Ex. A (denying the motion without prejudice and ordering the parties to come to an agreement following submission of the claim construction briefs); *Bonutti Skeletal Innovations LLC v. Arthrex, Inc.*, No. 13-cv-620 (M.D. Fla. March 25, 2014.) (D.I. 90 at Ex. B (denying the motion without prejudice and ordering that defendant may file similar motion seeking similar relief should the parties not come to an agreement post claim construction order).

E. Endo's Request to Modify Its List of Asserted Claims After Expert Reports Should be Rejected

Endo requests that if the Court mandates a reduction of asserted claims now, it must be able to later modify the claims it asserts, essentially adding new claims, after expert reports are

complete. (D.I. 89 at 7.) This makes no sense. If Endo is allowed to add asserted claims after expert reports are complete, the entire expert report process will need to be repeated with regard to the new claims. Endo's request would not only delay this case, but would also allow Endo to review Defendants entire case and then provide Endo with, essentially, another bite at the apple by allowing them to then assert different claims. Endo's request in this regard should be rejected.

III. CONCLUSION

Defendants have demonstrated many examples of the duplicative claims in the asserted patents, and under *Katz*, Endo is required to show that the asserted claims raise unique questions of validity or infringement. Endo has failed to do so. Instead, Endo has admitted that the claims are redundant and may be substantially reduced without materially affecting Endo's case. As such, Defendants respectfully request that the Court order Endo to limit the number of asserted claims to five or fewer per each of the '122, '216 and '482 patents.

Dated: September 12, 2014

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this 12TH day of September, 2014, I served the foregoing REPLY BRIEF IN SUPPORT OF DEFENDANTS' MOTION FOR REDUCTION IN THE NUMBER OF ASSERTED CLAIMS and Declaration of Paul B. Sudentas with exhibits in support thereof, by causing a copy of the same to be delivered via email to:

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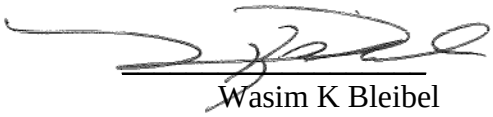

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